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| APPLICATION NO. | FILING DATE                                    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|--|----------------------|---------------------|------------------|
| 09/402,563      | 10/05/1999                                     | LEO K. VAN ROMUNDE   | SCQ-001USRCE        | 6102             |
|                 | os9 7590 05/11/2007<br>LAHIVE & COCKFIELD, LLP |                      | EXAMINER            |                  |
| ONE POST OF     | FICE SQUARE                                    |                      | WU, R               | UTAO             |
| BOSTON, MA      | 02109-2127                                     |                      | ART UNIT            | PAPER NUMBER     |
| . •             |  | ,                    | 3628                |                  |
|                 |  |                      |                     | •                |
|                 | • .  |                      | MAIL DATE           | DELIVERY MODE    |
|                 |  |                      | 05/11/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(a)   |  |  |  |  |
|--|---|--|--|--|--|--|
| ·  | Application No.   | Applicant(s)   |  |  |  |  |
|  | 09/402,563  | VAN ROMUNDE ET AL.   |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |
|  | Rob Wu  | 3628   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 Fe   | Responsive to communication(s) filed on <u>21 February 2007</u> .   |  |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This   | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |
| ,  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |
| . 4)⊠ Claim(s) <u>1-3,5-10,12-14,16 and 17</u> is/are pending in the application.  |   |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-3,5-10,12-14,16 and 17</u> is/are rejected.  |   |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |   |  |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | r election requirement.   |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examine  | r   |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |
| 12)  Acknowledgment is made of a claim for foreign   | priority under 35 U.S.C. § 119(a)   | )-(d) or (f)   |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:   |   |  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |   |  |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |
|  |   |  |  |  |  |  |
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| Attachment(s)  |   |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)   | Paper No(s)/Mail Da 5) Notice of Informal P   |  |  |  |  |  |
| Paper No(s)/Mail Date  | 6) Cther:   |  |  |  |  |  |

### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 21 2007 has been entered.

### Response to Arguments

- 2. Applicant's arguments, see page 5, filed February 21 2007, with respect to claims 1, 7, 10, and 12 have been fully considered and are persuasive. The 35 U.S.C. §112 second paragraph rejection of claims 1, 7, 10 and 12 has been withdrawn.
- 3. Applicant's arguments filed February 21 2007 have been fully considered but they are not persuasive.

The applicant argues that McIlroy et al (U.S. Pat No. 5,583,758 hereinafter 'McIlroy") does not teach the limitations presented in claims 1 and 12. The Examiner respectfully disagrees. Since claim 1 and 12 recite similar limitations the Examiner will focus the response on claim 1, however the response also applies to claim 12.

Claim 1 recites:

Art Unit: 3628

A method for electronically storing, retrieving and/or modifying records using a computer system comprising a display unit, an input unit, a memory unit and a processing unit; McIlroy teaches this limitation at column 4 lines 50-56)

Involving at least one recorded catalogue of recommended actions; Mcllory teaches this limitation by disclosing "a treatment component that presents the guideline treatment options, and highlights the guideline-selected option(s) based on user responses to questions." (col 6: lines 4-6) and "The treatment component also uses data bases. FIG 7 is an example of a guideline treatment data base set for the condition corresponding to guideline. In general, for each guideline identified by a five digit number in field 25, there are listed one or more treatment options. " (col 7: lines 13-17) The treatment component as disclosed by Mcllory include lists of treatment options, and therefore teach at least one recorded catalogue of recommended actions.

And for sequentially steering a process of interrelated actions from said at least one recorded catalogue of recommended actions; Mcllory teaches the limitation by disclosing "the system presents each guideline in a questioning logic sequence where the response to each question drives to the next question or to the appropriate treatment options. (col 5: lines 33-35)

Wherein said at least one recorded catalogue of recommended actions comprises hierarchised [sic] sequences of alternative actions. The Examiner cannot find the definition of hierarchised in a dictionary. The closest word to hierarchised in the Merriam Webster's Collegiate Dictionary Tenth edition is hierarchized, which means to arrange in a hierarchy. Therefore, the Examiner

takes hierarchised to mean to arrange in order or series. Mcllory teaches said limitation. In FIG 15 of Mcllory's invention, it can be seen that a list of recommended actions are shown (2A, 2B, 2C, 4A), within the list of recommended actions, actions 2C and 4A are alternative actions since 2A and 2B are chosen as the recommended treatments. It is also clear that Mcllory's actions are an ordered sequence of actions because the actions are labeled as 2A, 2B, 2C and 4A.

Wherein said actions comprise sequential procedure steps and wherein for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms. Mcllory teaches the limitation. From FIG 16 of Mcllory's invention it can see that the actions comprise sequential procedure steps. For example, action 2B calls for sequential procedure steps of "Streptokinase or urokinase for 3 days followed by 6 days heparin with coumadin initiated by day 2 of heparinization." Mcllory teaches for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms by disclosing that reports that show diagnostic decision outcome profiles and procedure decision outcome profiles are generated. (col 16: lines 57-59; Fig 24A)

Wherein said evaluation forms comprise a list of one or more selected from the group comprising of recommended actions, information-input requests, decision-requests and selection algorithms. Mcllory teaches the limitation by

Application/Control Number: 09/402,563 Page 5

Art Unit: 3628

showing that in FIG 24A the form that shows recommended actions, information-input requests and decision-requests (Proposed Treatment and Recommended Treatment)

And wherein said generation of evaluation form is carried out in function of said hierarchised [sic] sequences of alternative actions, and in function of the past history of all alternative actions, including both the actual treatment chosen and all other treatment not chosen by the user. Mcllory disclose in FIG 24A a specialist review work sheet that shows a recording of the sequences made before, during, and after the selection process, allowing for reconstruction of the whole decision making sequence including the sections thereof comprising alternatives that were not chosen in the end. In FIG 24A the actions that let up to the treatments are recorded and shown (239 and 240), the recommended treatment is recorded and shown (237) and the alternative treatments that are not chosen by the user are also recorded and shown (238)

so as to enable transfer of a group of evaluation forms and subforms in one operation into one file. Since Mcllory disclose the specialist review work sheet it is obvious to one skilled in the art that the evaluation forms and subforms are transferred in one operation into one file.

# Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3628

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 12 recites the phrase "and/or" in line 1, it is unclear whether the limitation "modifying" is necessary or optional.

Claims 1 and 12 recite, "where said actions comprise sequential procedure steps" it is unclear which actions "said actions" is referring to, recommended actions, or alternative actions or both.

Claims 1 and 12 recites the limitation "the actual treatment" in second to the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

## Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 1-3, 5-10, 12-14, 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat No. 5,583,758 to McIlroy et al.

As per claims 1, 12,

Art Unit: 3628

A method for electronically storing, retrieving and/or modifying records using a computer system comprising a display unit, an input unit, a memory unit and a processing unit; McIlroy teaches this limitation at column 4 lines 50-56)

Involving at least one recorded catalogue of recommended actions; McIlory teaches this limitation by disclosing "a treatment component that presents the guideline treatment options, and highlights the guideline-selected option(s) based on user responses to questions." (col 6: lines 4-6) and "The treatment component also uses data bases. FIG 7 is an example of a guideline treatment data base set for the condition corresponding to guideline. In general, for each guideline identified by a five digit number in field 25, there are listed one or more treatment options. " (col 7: lines 13-17) The treatment component as disclosed by McIlory include lists of treatment options, and therefore teach at least one recorded catalogue of recommended actions.

And for sequentially steering a process of interrelated actions from said at least one recorded catalogue of recommended actions; McIlory teaches the limitation by disclosing "the system presents each guideline in a questioning logic sequence where the response to each question drives to the next question or to the appropriate treatment options. (col 5: lines 33-35)

Wherein said at least one recorded catalogue of recommended actions comprises hierarchised [sic] sequences of alternative actions. McIlory teaches said limitation. In FIG 15 of McIlory's invention, it can be seen that a list of recommended actions are shown (2A, 2B, 2C, 4A), within the list of recommended actions, actions 2C and 4A are alternative actions since 2A and

2B are chosen as the recommended treatments. It is also clear that Mcllory's actions are an ordered sequence of actions because the actions are labeled as 2A, 2B, 2C and 4A.

Wherein said actions comprise sequential procedure steps and wherein for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms. Mcllory teaches the limitation. From FIG 16 of Mcllory's invention it can see that the actions comprise sequential procedure steps. For example, action 2B calls for sequential procedure steps of "Streptokinase or urokinase for 3 days followed by 6 days heparin with coumadin initiated by day 2 of heparinization." Mcllory teaches for each of said steps the method generates electronic evaluation forms hierarchically organized as forms and subforms by disclosing that reports that show diagnostic decision outcome profiles and procedure decision outcome profiles are generated. (col 16: lines 57-59; Fig 24A)

Wherein said evaluation forms comprise a list of one or more selected from the group comprising of recommended actions, information-input requests, decision-requests and selection algorithms. Mcllory teaches the limitation by showing that in FIG 24A the form that shows recommended actions, information-input requests and decision-requests (Proposed Treatment and Recommended Treatment)

And wherein said generation of evaluation form is carried out in function of said hierarchised [sic] sequences of alternative actions, and in function of the past history of all alternative actions, including both the actual treatment chosen and all other treatment not chosen by the user. Mcllory disclose in FIG 24A a specialist review work sheet that shows a recording of the sequences made before, during, and after the selection process, allowing for reconstruction of the whole decision making sequence including the sections thereof comprising alternatives that were not chosen in the end. In FIG 24A the actions that let up to the treatments are recorded and shown (239 and 240), the recommended treatment is recorded and shown (237) and the alternative treatments that are not chosen by the user are also recorded and shown (238)

so as to enable transfer of a group of evaluation forms and subforms in one operation into one file. Since Mcllory disclose the specialist review work sheet it is obvious to one skilled in the art that the evaluation forms and subforms are transferred in one operation into one file.

As per claims 2, 13, McIlroy, et al discloses:

Wherein said at least one recorded catalogue of recommended actions comprise associated electronic selection algorithms in respect of the hierarchised sequences of alternative actions...(col. 3, line 2-4).

As per claim 3, 14, McIlroy, et al discloses:

Art Unit: 3628

Wherein said selection algorithms are integrated in said generated electronic forms...(Figs 10-17).

As per claim 5, 16, McIlroy, et al discloses:

Wherein said evaluation form comprises information from records relevant for a decision-request...(col. 5, lines 56-65).

As per claim 6, 17, McIlroy, et al discloses:

Wherein a record of information entered and used is stored in said memory unit... (col. 4, lines 56-59).

As per claim 7, McIlroy, et al discloses:

Wherein a record of the information and actions entered and used is stored in the memory unit of the purpose of measurement of the effectivity and/or efficiency of effects and/or results of the procedure...(col. 18, lines 16-20).

As per claim 8, McIlroy, et al discloses:

Wherein the method involves a supervising organization for the purpose of quality control and quality improvement...(col. 18, lines 20-22).

As per claim 9, McIlroy, et al discloses:

Wherein the method allows for updating of the recorded catalogue(s) of recommended actions... (col. 10, lines 14-15).

As per claim 10, McIlroy, et al discloses:

Wherein said supervising organization evaluates the effectivity and/or efficiency of effects and/or results based on said records of information and actions used/entered,

stored during use of the method, and updates the recorded catalogue(s) of recommended actions in function of said evaluation...(col. 3, lines 21-25).

#### Conclusion .

8. Examiner's Note: Examiner has cited particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant.

Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that the applicant, in preparing the responses, fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rob Wu whose telephone number is (571)272-3136.

The examiner can normally be reached on Mon-Fri 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Hayes can be reached on (571)272-6708. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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